

REMARKS

Claims 1-28 and 30 are pending in the present application. Each of the following rejection is discussed in more detail below.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-28 and 30 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Office rejected claims 1 and 4 for reciting a complex selected from micelles, vesicles, emulsion, gel and matrix. Applicants respectfully disagree. To expedite prosecution and for clarity, claims 1 and 4 have been amended to indicate that hydration of the composition forms a complex between the photosensitizer and the carrier.

As the Office indicated, hydration of the composition forms one product. (Office Action, Remark 2). In amended claim 1, hydration of the composition forms one product, which is a complex between the photosensitizer and the carrier. The complex may be in a different forms, such as a micelle, vesicle, emulsion, gel or matrix. Accordingly, the claims are definite, and Applicants respectfully request that this rejection is withdrawn.

Obviousness Double Patenting

Claims 4-7, 16-18, 26-28, and 30 were rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-13 of U.S. Patent No. 6,693,093. Applicants respectfully request that this rejection be held in abeyance until allowance of the claims, at which time Applicants will submit a terminal disclaimer to obviate this rejection.

Rejections under 35 U.S.C. § 103(a)

Claims 1-28 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schneider (U.S. 6,258,378) (“Schneider”), by itself or in combination with Lyons (U.S. 5,616,342) (“Lyons”) and Young (U.S. 6,375,930) (“Young”). Applicants respectfully disagree.

First, there is no motivation to combine the Schneider, Lyons and Young references. The Schneider reference teaches formulations comprising an aqueous suspension of gas-filled microspheres and liposomes filled with a bioactive substance. The formulation is delivered to a target site, followed by application of ultrasound pulses to the site, causing the gas in the microspheres to explode. Consequently, the liposome vesicles are opened, releasing the drug at the target site. (See e.g., Abstract and claim 1 in the '378 patent). The Schneider reference does not relate to photosensitizers at all, let alone photosensitizer formulations. In contrast, the Lyons and Young both relate to photosensitizer compositions.

Even if combined, the combination fails to teach all the elements of the claimed invention. In particular, the combination fails to teach a dried photosensitizer-carrier composition, comprising a mixture of a polypyrrolic macrocyclic photosensitizer and a copolymer carrier that is physically associated with a solid support. The Young reference is silent regarding the use of copolymers at all. Schneider and Lyons only teach the use of poloxamers as surfactants or emulsion stabilizers. (See, '378 at col. 7:1-4; see also, '342 patent at col. 8:17-22).

For example, Lyons teaches the preparation of an emulsion comprising tin ethyl etiopurpurin in oil. (See, '342 patent at col. 10:31-67). The oil-in-water emulsions also contains a surfactant to stabilize dispersed droplets in the emulsion. ('342 patent at col. 2:30-34 and col. 8:17-22). However, the emulsion itself is formed from oil and water, and the stabilizer is not itself emulsified. Similarly, the surfactants in Schneider are not part of any complex formation, and are only used to facilitate lipid solubilization and gas microbubble formation, and are removed after microbubble formation. ('378 patent at col. 13:6-8). Thus, the surfactants in the Schneider and Lyons references are distinguishable from carriers that are complexed with a photosensitizer to form a dried photosensitizer-carrier complex associated with a solid support, wherein the complex may form an emulsion upon hydration.

Furthermore, even if combined, there is no reasonable expectation of success. Although certain block copolymers have previously been used as emulsion stabilizers, block copolymers which themselves emulsify in aqueous suspension have not been studied in detail. Block

copolymers were not expected to be useful as such because of the greater difficulty in controlling and maintaining particle size during manufacture and storage. (See, Specification at page 47:24-28).

Based on the above, claims 1-28 and 30 are not obvious under Schneider, alone or in combination with the Lyons and Young references. Thus, Applicants respectfully request that this rejection be withdrawn.

Claims 1-10, 16-28, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lyons in combination with Klaveness (U.S. 5,674,468) and/or See (U.S. 6,015,576). Applicants again respectfully disagree.

There is no motivation to combine the references, which are non-analogous art. In particular, the Lyons reference relates to emulsion formulations for administering poorly soluble photosensitizing compounds. On the other hand, Klaveness *et al.* relate to contrast agents comprising gas-containing or gas-generating polymers. (See Abstract in the '468 patent). The See reference relates to methods for inducing a systemic immune response to an antigen. Neither the Klaveness or the See reference relates to photosensitizing compounds.

Even if combined, the combination fails to teach the invention as claimed. As the Office acknowledged, the Lyons reference does not teach the preparation of a composition in a dried form in the presence of solid supports such as lactose. (Office Action, Remark 5, assuming the term "McCarty" refers to the Lyons reference). Furthermore, as previously indicated, the Lyons reference does not teach the use of various copolymers as carriers which themselves emulsify upon hydration with an aqueous medium.

The Office cites to the '468 patent to Klaveness at col. 40:28-45 as support for the teaching that emulsions can be lyophilized in the presence of lactose. Applicants respectfully disagree. However, unlike the invention as claimed which is directed to a dried polypyrrolic macrocyclic photosensitizer-copolymer carrier complex, Klaveness teaches a naphthalene emulsion, wherein a naphthalene solution is emulsified into a water solution containing PLURONIC®. ('468

patent at col. 40:30-34). The naphthalene droplets subsequently solidified into beads, which were suspended in a lactose solution, frozen into a block, and freeze-dried. ('468 patent at col. 40:37-44). Naphthalene and polypyrrolic macrocycles are different compounds, and naphthalene is not a polypyrrolic macrocycle. Thus, there is no reasonable expectation of success that naphthalene and a polypyrrolic macrocycle would each behave similarly in an emulsion, and/or when lyophilized in an emulsion.

The Office also cites to the See reference as support for the teaching that emulsions can be lyophilized in the presence of lactose to stabilize the emulsions. However, the See reference refers to the lyophilization of an emulsion comprising liposomal antigen. ('576 patent at col. 57-60). The See reference is silent regarding photosensitizers a triblock copolymer, let alone a dried photosensitizer-carrier composition on a solid support, which upon hydration forms a complex in the form of micelles, vesicles, emulsion, gel or matrix.

Based on the above, claims 1-10, 16-28, and 30 are not obvious under the Lyons in combination with Klaveness and/or See. Applicants therefore, respectfully request that this rejection be withdrawn.

Claims 1-10, 16-28, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lyons in view of either Desai (U.S. 6,074,666) or Madden (U.S. 5,389,378) in further combination with Unger (U.S. 6,028,066). Applicants again respectfully disagree.

The teachings of the Lyons reference have been discussed above. The failure of Lyons to teach the invention as claimed is not remedied by the combination of Desai or Madden, in further combination with Unger. As previously indicated, the Lyons reference only teaches the use of poloxamers as emulsion stabilizers. (See, '342 patent at col. 8:17-22). Likewise, the Unger reference only teaches the use of poloxamers as emulsion stabilizers. (See, '066 patent at col. 40:41-col. 41:12). The Desai and Madden references are entirely silent regarding poloxamers.

Thus, none of these references, alone or in combination teaches a dried photosensitizer-carrier composition comprising a mixture of a polypyrrolic macrocyclic photosensitizer and a

copolymer carrier that is physically associated with a solid support. Furthermore, as previously indicated, there is no reasonable expectation of success that block copolymers will themselves emulsify in aqueous suspension. (See, Specification at page 47:24-28).

Based on the above, claims 1-10, 16-28, and 30 are nonobvious under Lyons in view of either Desai or Madden, in further combination with Unger. Applicants therefore, respectfully request that this rejection be withdrawn.

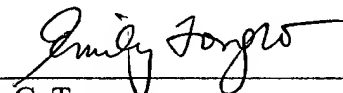
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012011700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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